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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,133	06/11/2002	Lisa E. Myers	1038-1102 MIS:jb	9490

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EXAMINER	
PAK, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,133	MYERS ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 10, drawn to a purified and isolated nucleic acid, a vector, a transformed host, a method of forming a substantially pure recombinant transferrin receptor protein, and a diagnostic kit, classified in Class 435, subclass 69.1.

II. Claim 6-8 and 12 and 14, drawn to a recombinant transferrin receptor, classified in Class 530, subclass 350.

III. Claims 7, 8, 11 and 13, drawn to an immunogenic composition, and a method for generating an immune response, classified in Class 514, subclass 44.

IV. Claims 9, drawn to a method of determining the presence of a nucleic acid, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons.

The products of inventions I and II, are distinct each from the other, because they are drawn to products having materially different structures and functions.

The products of inventions I and III, are distinct each from the other, because they are drawn to products having materially different structures and functions or the Group III comprises additional immunogen carrier compounds which are necessary for the practice of the invention.

The products of inventions I, and the process of invention III or IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA and vector of invention I can be used for producing recombinant proteins.

The transformed host product of inventions I is not used in or produced by any one of the processes of inventions III or IV, and is distinct from each other.

The methods of inventions I, III, and IV, are distinct, each from the other, because they are drawn to processes having materially different process steps, which are practiced for materially different purposes.

The products of inventions II and III, are distinct each from the other, because they are drawn to products having materially different structures and functions or the Group III comprises additional immunogen carrier compounds which are necessary for the practice of the invention.

The process of inventions I, and any one of the products of inventions II or III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be used to make a materially different process such as by a chemical peptide synthesizer.

The product of inventions II is not used in or produced by the process of invention IV, and is distinct from each other.

The products of inventions II, and the process of invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the protein of invention II can be used for transferrin binding assays.

The products of inventions III and IV, are distinct each from the other, because invention IV contains additional pharmaceutically acceptable carrier product which are necessary for the practice of the invention. Furthermore, the product of invention IV are limited to use in a method of administering the pharmaceutical composition of invention IV, while the product of invention III may be used for other purposes such as generating antibodies.

The immunogenic composition product of inventions III is not used in or produced by the process of invention IV, and is distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for any one of inventions I-IV is not required for any other invention I-IV, restriction for examination purposes as indicated is proper.

In the event Group III is elected, applicants are required to elect as follows:

Claims 22 and 23 are generic to a plurality of disclosed patentably distinct species comprising:

A) a purified and isolated nucleic acid molecule, classified in Class 514, subclass 44;

B) a recombinant transferrin receptor, classified in Class 424, subclass 251.1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These species are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for species A is not required for species B; thus, the restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
29 September 2005